

- 1 -

## A FRACTURE FIXATION DEVICE IN WHICH A FIXATION PIN IS AXIALLY RESTRAINED

### FIELD OF THE INVENTION

The invention relates to a fixation device for fixing a fracture in a bone structure and more particularly to a fixation pin for penetrating an unstable bone fragment for being secured to a stable bone fragment, the pin having an end which extends out of the bone structure and is restrained by a fixation plate.

The invention also relates to a method of fixing a bone fracture utilizing such a pin and plate.

### BACKGROUND AND PRIOR ART

In my earlier patent 5,931,839, there is disclosed an implantable fixation device which comprises a K-wire or pin for fixation of a bone fracture and a fixation plate for engaging the end of the pin which extends from the bone structure. In the patent, the protruding end of the pin is engaged in a hole in the fixation plate such that the pin is free to axially travel in the hole. In order to prevent separation of the pin from slipping out of from under the hole in the plate, the end of the pin can be bent while preserving the axial sliding capability of the pin in the hole in the plate.

Single K-wire fixation of bone fragments does not provide secure fixation, since the K-wire is secured only at a single end that can be at a considerable distance from the fracture site. The fixation or pin plate provides fixation of the K-wire at a second site, but has the disadvantage of requiring the K-wire to be bent over the edge of the plate or into an adjacent hole in the plate. This step requires backing out of the K-wire and is cumbersome and can lose reduction.

In addition, current pin plate designs allow the pin to back out with motion of the fracture. This can lead to abrasion of adjacent soft tissue structures and even tendon rupture.

#### SUMMARY OF THE INVENTION

An object of the invention is to provide a fixation means providing constraint of the K-wire adjacent to the site of entry into the unstable fracture fragment or at a position close thereto.

A further object of the invention is to secure the top of the protruding end of the K-wire to prevent translational movement of the K-wire as well as to prevent backing out of the wire into the soft tissues.

Another object of the invention is to provide a bend in the K-wire prior to placement of the fixation plate so that the K-wire need not be withdrawn from the bone, simplifying the procedure.

In accordance with the above and further objects of the invention, the fixation device for fixing a fracture in a bone structure comprises a fixation pin adapted for penetrating through an unstable bone fragment of the bone structure across a fracture into a stable bone fragment, the pin having one end secured to the stable bone fragment and an opposite end extending out from the unstable bone fragment, and a fixation plate adapted for being secured to the stable bone fragment at a distance from the outwardly extending end of the fixation pin. The outwardly extending end of the fixation pin is smooth and the fixation plate is engageable with the end of the pin to prevent the pin from backing out of the unstable bone fragment while providing restraint against movement of the pin in the plane of the plate.

In further accordance with the invention, the end of the pin is bent and the fixation plate has means for engaging the bent end of the fixation pin.

According to one feature of the invention, the means for engaging the bent end of the fixation pin is constituted by a lower surface of the fixation plate which bears against the bent end of the fixation pin to restrain the pin with respect to the bone structure.

According to a further feature of the invention, the means for engaging the bent end of the fixation pin comprises a groove in the fixation plate for receiving the bent end of the pin.

A further feature of the invention is that the bent end of the fixation pin extends substantially parallel to the underlying bone structure.

According to another embodiment of the invention, the end of the pin is straight and it is engaged in an opening in the plate and secured in the opening by crimping the plate.

According to another embodiment of the invention, the pin is cut where it protrudes through a hole or groove in the plate and welded in situ to the plate to prevent it from backing out.

In another aspect of the invention, a method is provided for fixing the fracture which method comprises inserting a fixation pin into the bone structure across a fracture and leaving an end of the pin extending from the bone structure, securing a fixation plate to the bone structure at a distance from the extending end of the fixation pin, and engaging the fixation plate with the portion of the pin to prevent the pin from backing out of said bone structure while providing restraint against movement of said pin in the plane of the plate.

#### BRIEF DESCRIPTION OF THE FIGURES OF THE DRAWING

Figure 1 is a side elevational view showing a conventional K-wire placed in bone structure.

Figure 2 shows an end of the K-wire bent over at the entry site of the pin in the bone structure.

Figure 3 shows, partially broken away and in section a locking or fixation plate secured to the bone structure.

Figure 3A is an end view from the left in Fig. 3 from the left in Fig. 3 showing

the engagement of the fixation plate and the K-wire.

Figure 4 is a modification of the bent portion of the K-wire in which the bent portion extends beyond the fracture in the bone structure.

Figure 5 shows another embodiment of the fixation plate engaging the bent portion of the K-wire.

Figure 6 shows another embodiment of engagement of the fixation plate and the bent portion of the pin.

Figure 6A shows another embodiment of engagement of the fixation plate and the end of the pin.

Figure 7 shows another embodiment of the engagement of the fixation plate and the K-wire.

Figure 8 shows a further embodiment of the engagement of the fixation plate and the K-wire.

Figure 9 is a sectional view taken along line 9-9 in Figure 8.

Figure 10 is a top plan view of Figure 8.

Figure 11 shows another embodiment of the engagement of the fixation plate and the K-wire.

Figure 12 shows a further embodiment of the engagement of the fixation plate and the K-wire.

Figure 13 is an end view of Figure 12.

Figure 14 is a plan view of Figure 12.

Figure 15 shows a further embodiment of the engagement of the fixation plate and the K-wire.

Figure 16 is an end view of Figure 15.

Figure 16A is similar to Figure 16 and shows a modification thereat.

Figure 17 is a plan view of Figure 15.

Figure 18 shows a modified version of the embodiment shown in Figure 15.

Figure 19 is an end view of Figure 18.

Figure 20 is a plan view of Figure 18.

Figure 21 shows another embodiment of engagement of the fixation plate and the K-wire.

Figure 22 is an end view of Figure 21.

Figure 23 is a plan view of Figure 21.

Figure 24 shows another embodiment of engagement of the fixation plate and the K-wire.

Figure 25 is an end view of Figure 24.

Figure 26 is a plan view of Figure 24.

Figure 27 is a side elevation view showing another embodiment of the fixation plate.

Figure 28 is a top plan view of Figure 27 in a preliminary stage of assembly of the fixation plate and pin.

Figure 29 shows Figure 28 after completion of the assembly.

Figure 30 shows a modified embodiment of Figure 29 in a preliminary stage of assembly.

Figure 31 shows Figure 30 after completion of assembly.

Figure 32 is an end view of a modified embodiment of Figure 16 in a preliminary stage of assembly of the pin and fixation plate.

Figure 33 is a plan view of Figure 32.

Figure 34 shows Figure 32 after completion of assembly.

Figure 35 is a plan view of Figure 34.

#### DETAILED DESCRIPTION

Referring to Figure 1 therein is seen a bone structure 1 having a fracture 2 therein forming a stable bone fragment 3 and an unstable bone fragment 4 on opposite sides of the fracture 2. In order to provide fixation of the unstable bone fragment 4 to the stable bone fragment 3, a K-wire or pin 5 is inserted through the unstable bone fragment 4 across the fracture 2 into the stable bone fragment 3. The end of the pin 5 which engages in the stable bone fragment 3 can be smooth or threaded to insure its anchorage in the stable bone fragment. After the pin 5 has been secured in the bone structure and the fracture 2 has been reduced, the part of the pin 5 extending from the anterior surface of the bone structure is severed and bent to form a bent portion 6. The bent portion 6 is bent at an angle so that the bent portion 6 will be substantially parallel to the superficial surface of the bone structure 1 and be capable of engagement thereon as shown in Figure 2. In order to secure the protruding end of the pin 5, a fixation plate 10 is fixedly secured to the stable bone fragment 3 by bone screws 11 or equivalents thereof, such as pins, wires, blades, staples, brackets and the like as well known in the art. The fixation plate 10 is provided with a groove 12 in its lower surface at an end of the plate so that the bent portion 6 of the pin can be engaged in the groove 12 to

secure the pin against translational movement in the plane of the plate and to prevent the pin from backing out of the bone structure by an axial movement of the pin out of the bone structure.

The term "pin" used herein refers to pins, wires, nails with or without heads, and a thin screw or the like. The difference between "pins" and rigid elements, such as screws, blades and the like is in the thickness or diameters thereof. In order to simplify the description, the term "pin" is intended to cover all of the above and similar devices in the description herein flexible enough to allow the surgeon to bend the pin at the site where it exits from the bone. The term K-wire describes a smooth, fully or partially threaded wire element of uniform diameter that is stiff enough to drill or impact into bone.

Referring to Figure 4, herein the arrangement is similar to that in Figure 2 except that the bent portion 6' is of greater length and extends over the fracture 2 to adjoin the stable bone fragment 3. The fixation plate 10' is similar to that in Figure 3 but is shortened to receive only the end of the bent portion 6'. In this embodiment, the end of the bent portion 6' of the fixation pin is at a distance from the site of entry of the pin into the unstable bone fragment.

In Figures 3 and 5, the groove 12 is formed in the fixation plate at the lower surface of the fixation plate and the groove opens at the tip end of the plate to capture the end of the pin.

Figure 6 shows an embodiment in which fixation plate 20 is applied directly on the bent portion 6 of the pin without any groove. Effectively, the plate 20 clamps the bent portion 6 of the pin against the superficial surface of the bone fragment 4 of the bone structure 1.

In a modification shown in Figure 6A, the end of the pin 5 is not bent and the underside of the plate 20 is formed with a groove or dimple 21 on its undersurface to engage the protruding end of the pin and prevent the pin from sliding underneath the plate. Since the groove or dimple 21 is confined within the undersurface of the plate, the pin is prevented from backing out of the bone structure by the plate.

Figure 7 is a combination of the embodiments in Figures 1, 3 and 5 in that the bent portion 6 is engaged in the groove 11 of the fixation plate 30. However, the pin is inserted into the bone structure at a site outside the fixation plate but in proximity thereto.

Figures 8-10 show a modification in which a hole 13 is provided in the fixation plate 40 and connects with the groove 11 to receive a second bend portion 7 formed at the end of the pin 6A. This embodiment provides a secure engagement of the pin to further prevent the pin from slipping out from under the fixation plate.

Figure 11 shows another modification in which the pin is bent in a U-shape at 6B instead of lying flat as shown in Figure 2. The engagement of the bent portion 6B in the groove 11 and the restraint provided thereby is the same as in the previously described

embodiments.

Figures 12-14 show a modification of the embodiment in Figure 11 in which an elongated groove 14 is provided in the upper surface of the plate. The groove 14 is slightly undersized with respect to the diameter of the pin, so that the bent portion of the pin is frictionally gripped in the groove 14 thereby restraining the pin in the fixation plate.

Figure 15 shows a fixation plate 50 having longitudinally extending tabs 51 and 52 thereon in transversely spaced relation as shown in Figure 16. The tabs are at different levels and face inwardly in opposite directions to engage the bent portion 6C of the fixation pin from above and below to grip the bent portion. In this embodiment, the bent portion of the pin extends transversely of the fixation plate and the engagement of the bent portion 6C with the fixation plate takes place transversely of the entry site of the fixation pin into the bone structure 1.

Figure 16A is similar to Figure 16 except that the terminal end of the pin is bent at 6D to restrain the pin and prevent the pin from slipping out from the tabs.

Figures 18-20 show a modification of the embodiment illustrated in Figures 15-17 in that the tabs 51 and 52 are placed at the same level and the pin is bent at 6E so as to be gripped from above and below by the tabs and be securely held in position thus being prevented from undergoing lateral displacement.

Figures 21-23 show an embodiment in which the fixation plate 70 is formed at its end with a groove 71 which has side surfaces 72 and 73, which as viewed in Figure 22, taper in narrowing manner from the lower surface of the fixation plate to the upper surface thereof. As seen in Figure 23, the side surfaces 72 and 73 also narrow in a V-shape in a direction from the end of the fixation plate 70 inwardly thereof. When the bent portion 6F of the pin is inserted into the groove 71, it becomes locked therein as the plate 70 is screwed down. The bent portion 6F of the pin can be provided with a barb 74 to engage the fixation plate and lock the pin and further prevent the pin from backing out of the bone structure.

Figures 24-26 illustrate a further embodiment in which fixation plate 80 is provided with a transverse groove 81 extending through the fixation plate to receive a transverse bend portion 6G of the fixation pin. In this embodiment, the fixation plate 80 is provided with transverse groove 81 as well as with longitudinal groove 11 to enable the fixation plate to be employed in the arrangement as shown in Figures 24-26 as well as in the arrangement shown in Figure 7.

Figures 27-35 show several embodiments in which instead of bending an end of the pin and engaging the bent end by the fixation plate, the end of the pin is straight and it is secured to the fixation plate by crimping the fixation plate.

Figures 27 and 28 show a fixation plate 90 similar to those described earlier except that the plate has a bore 91 therein in which the fixation pin 5 is slidably engaged. The end of the pin is straight and not bent as in the previously described embodiments. In order to

secure the pin 5 and prevent it from backing out of the bone structure or sliding in the plane of the plate a crimping tool 92 engages the plate 90 around the hole 91 and a crimping force F is applied to the plate 90 to deform the plate at crimps 93 and cause the hole 91 and pin 5 to be deformed and clamped together so that the pin is secured against backing out of the bone structure or sliding in the plane of the plate.

Instead of receiving the pin 5 in the hole 91 as shown in Figure 27, the end of the plate 100 can be formed with an open groove 101 as shown in Figure 30. After crimping, the legs 102 of the plate on both sides of the groove 101 are crimped against the pin 5 to clampingly secure the pin in place.

An alternative in either of the embodiments in Figure 28 or Figure 30 is to cut the pin at the level of the hole and weld the pin to the plate.

In the embodiment shown in Figures 32-35, the pin 5 extends through a groove 110 in the end of a fixation plate 111. The end of the plate 111 is formed with longitudinally extending tabs 112, 113 defining the groove 110. The tabs 112, 113 straddle opposite sides of the pin 5. As seen in Figure 32 two tabs 112 are arranged one above the other at one side of the pin 5 and one tab 113 is at the opposite side of the pin at a level between the tabs 112. After crimping, the tabs 112, 113 and pin 5 are deformed as shown in Figures 34 and 35 and the end of pin 5 is clampingly engaged with tabs 112, 113.

The invention has been described with reference to a number of embodiments

adapted for use with pins for fixing unstable bone fragments to stable fragments. These embodiments solve the problem in the use of these pins due to bending migrating and backing out into the soft tissues. The embodiments of the invention serve to prevent bending and migration of a flexible pin as well as migration of the pin into the soft tissues.

Although the invention is disclosed with reference to particular embodiments thereof, it will become apparent to those skilled in the art that numerous modifications and variations can be made which will fall within the scope and spirit of the invention as defined by the attached claims.

RECORDED IN U.S. PATENT AND TRADEMARK OFFICE